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10/530,554	04/07/2005	Hiroyuki Sato	10936-86	8861
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DINSMORE & SHOHL, LLP			MESH, GENNADY	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,554	Applicant(s) SATO ET AL.
	Examiner GENNADII MESH	Art Unit 1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 May 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,4 and 6-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,4 and 6-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-146/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Response to Amendment

Applicant's amendment filed on May 27, 2008 is acknowledged.

Claims 1, 4 and 6-22 are pending. Claims 2,3 and 5 have been canceled by Applicant.

Rejection is maintained as it was set forth in previous Office action mailed on November 26, 2007.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1,4, 6 and 10 - 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) and in further view of Handbook of Thermoplastic Polymers, Chapter 2, pages 80 –94(hereafter HTP).

Regarding Claim 1 and 4 Shinoda discloses preparation (see abstract) process of polyester with desirable MW(molecular weight) or melt viscosity(note, that melt viscosity of a **resulting aliphatic polyester** polymer is proportional function of the MW of the polyester) from cyclic esters or their mixtures (see lines 5 –15,column 1), wherein impurities as water and hydroxycarboxylic acids (including oligomers) are accurately controlled (thus proton concentration also controlled) with total amount less than 100 ppm (see abstract, lines 40 – 68,column 2, line 5-7,column 3 and line 50,column 6) in order to produce polyester with desirable MW (see lines 1-5,column 3).

Shinoda is silent about addition of water to polymerization system. However, addition of water in order to start ring-opening polymerization process is known in the art. For example, Howelton teach addition of water (as polymerization initiator) in ring-opening polymerization(see line 20,column1).

Therefore, it would have been obvious to one of ordinary skill in the art to use purified cyclic ester in order to obtain polyester with desirable MW (or melt viscosity) per teaching of Shinoda and add water to polymerization system in order to start or/and increase rate of polymerization as it shown by Howelton.

Shinoda in view of Howelton silent about conducting polymerization in closed volume – particularly inside closed tubes as it claimed by Applicant in Claim 1 and 11.

However, ring –opening polymerization process can be conduct in closed volume, because process is not required evacuation of byproducts from polymerization system due to nature of this process – no volatile byproducts are generated during polymerization process as it disclosed in HTP (pages 90-94).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to conduct polymerization process disclosed by Shinoda in view of Howelton inside closed tubes (as a simple polymerization reactors), as it claimed by Applicant, due to significant reduction of overall cost of production equipment due to simplicity of this type or reactors(tube).

Regarding Claim 12 Shinoda in view of Howelton silent about conducting polymerization in solid state after initial polymer was produced.

However, solid-state polymerization of polyesters in order to increase MW (or melt viscosity) of the polymer is well known in the art and would be obvious extension of polymerization process as it disclosed in HTP(pages 80 –82).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to conduct polymerization process disclosed by Shinoda in view of Howelton with following step of solid-state polymerization as it thought in HTP in order to increase MW of the final polymer.

Subject mater claimed by Applicant in Claims 10 – 16 was discussed above. Also see Shinoda: lines 5-17, column 1; lines 20 – 25,column 6 and Example 6, wherein copolymer of glycolide and other cyclic monomer is disclosed.

Regarding Claims 17 – 20 : Shinoda in view of Howelton discloses substantially same process capable of producing substantially same product as a polyester with same MW. It will be reasonable to believe that other properties as viscosity and Yellowness index will be also substantially same. Burden shifts to Applicant provide factual results to the contrary.

2. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) and HTP(hereafter HTP), as applied to claims 1,4,6 and 10 –22 above, and further in view of Early (US 6,437,565).

Regarding Claims 7 – 9: as it shown by Shinoda in view of Howelton and HTP impurities and proton concentration -(see above) are controlled factor in preparation process of the polyester with desirable MW (or melt viscosity as it explained above –

see paragraph 1), but silent about regressional correlation between proton concentration and specific physical properties govern by MW of the polymer.

However, regressional analysis is a standard tool, routinely used in the art in order to determine relations between control factors and any functional properties. For example, Early discloses use of regressional analysis (see Fig.4) in order to determine physical properties of the composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use regressional analysis as taught by Early in order to find optimum amount of proton concentration in obtain polyester with desirable properties by production method disclosed by Shinoda in view of Howelton.

Response to Arguments

3. Applicant's arguments filed on May 27, 2008 have been fully considered but they are not persuasive.

3.1. Applicant's arguments related to Claims 1,4, 6 and 10 - 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) and in further view of Handbook of Thermoplastic Polymers, Chapter 2, pages 80 –94(hereafter HTP) based on alleged deficiency of each individual references.

However, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642

F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Specifically, as it explained in rejection above:

a) Shinoda disclosed process wherein polymer with desirable characteristics is obtained by **controlling impurities that contribute to overall proton concentration**:

"The cyclic ester compound used in the invention is preferably dehydrated as much as possible before subjecting to the polymerization reaction. When the moisture content is high, molecular weight control of polyester is liable to be difficult. Consequently, moisture content of the cyclic ester compound is preferably 0.5% by weight or less, more preferably 1,000 ppm by weight or less. **In order to accurately control the molecular weight of polyester having a molecular weight of 100,000 or more in particular, moisture content of the cyclic ester compound is preferably 100 ppm by weight or less.**" (Column 6, lines 39-50) – thus, first Applicant's argument is not persuasive.

Thus, Shinoda recognized that Molecular weight can be controlled if polymerization system contains less than **100 ppm of water** - this amount overlapping with amount of water claimed by Applicant.

b) Shinoda as a Primary reference does not need teach all elements of Applicant's Claims 1, 4,6 and 10-22. Adding water to the polymerization system was taught by Secondary reference as Howelton. Applicant's statement, that one of ordinary skill won't combine disclosure of Shinoda with teaching of Howelton is unpersuasive for following reasons: both references belongs to same art of polycondensation by ring-opening

mechanism, wherein water can be catalyst of ring opening polycondensation in both processes - this is why one of ordinary skill in the art could apply teaching of Howelton in order to modify process of Shinoda.

c). Note, HTP is not teaching away from adding water to polymerization system, as it stated by applicant - see page 14 of Arguments, but provide reasons for conducting at ring-opening polymerization process in closed volume, because process is not required evacuation of byproducts from polymerization system due to nature of this process – no volatile byproducts are generated during polymerization process – for this reason, it would be obvious , **based on this teaching**, to conduct polymerization in closed volume.

b) Note, when ring-opening polymerization is completed, all cyclic structures are opened – than low molecular weight polymers can be subjected to SSP (Solid state polymerization) as it routinely done in the art.

c) Regarding Applicant's argument that Shinoda use alcohol as a Molecular weight regulator – note, that language of Applicant's claims is open to any additional compounds and is not specifically exclude lauryl alcohol from claimed subject matter.

3.2. Regarding Applicant's arguments related to Claims 7-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda (US 5,412,067) in view of Howelton (US 5,342,918) as applied to claims 1,-6 and 13 –20 above, and further in view of Early (US 6,437,565).

As it was discussed in original rejection, Shinoda in view of Howelton teach that impurities and proton concentration (see above) are controlled factor in preparation

process of the polyester with desirable MW, but silent about regressive correlation between proton concentration and specific physical properties govern by MW of the polymer. Note, that regressive analysis is a standard tool, routinely used in the art in order to determine relations between control factors and any functional properties. For example, Early discloses use of regressive analysis (see Fig.4) in order to determine physical properties of the composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use regressive analysis as taught by Early in order to find optimum amount of proton concentration in obtain polyester with desirable properties by production method disclosed by Shinoda in view of Howelton.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GENNADIY MESH whose telephone number is (571)272-2901. The examiner can normally be reached on 10 a.m - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272 1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gennadiy Mesh
Examiner
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